

Claims

## 1. An embolic protection system comprising:-

5 a guidewire for advancing through a vasculature, the guidewire having a distal end and a proximal end;

10 an embolic protection filter having a filter body with a distal end and a proximal end, the filter body providing for a collapsed configuration and an expanded deployed configuration;

15 the embolic protection filter body having a guidewire path for slidably receiving the guidewire to permit movement of the filter relative to the guidewire when the filter is in the collapsed configuration and the expanded deployed configuration;

20 a delivery catheter advanceable over the guidewire for delivery of the embolic protection filter; the delivery catheter having a proximal end and a distal end, the filter being deployed from the distal end of the delivery catheter into the expanded deployed configuration;

25 a retrieval catheter advanceable over the guidewire for retrieval of the filter, the retrieval catheter having a distal end and a proximal end; and

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engagement elements for engaging the embolic protection filter with the guidewire for retrieval of the filter into the retrieval catheter in the collapsed configuration.

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2. An embolic protection system as claimed in claim 1 wherein the guidewire path is in isolation from the embolic material captured within the filter body.

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An embolic protection system as claimed in claim 1 or 2 wherein the tubular guidewire path is defined by a tubular sleeve.

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4. An embolic protection system as claimed in claim 3 wherein the tubular sleeve extends from the proximal end to the distal end of the filter.

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An embolic protection system as claimed in any preceding claim wherein the guidewire path is a tubular guidewire path.

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6. An embolic protection system as claimed in any preceding claim wherein the engagement elements comprise a guidewire engagement element on the guidewire and a filter engagement element on the filter, the engagement elements co-operating to provide selective engagement and positioning of the filter with respect to the guidewire.

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7. An embolic protection system as claimed in claim 6 wherein the engagement element of the guidewire comprises a guidewire abutment on the guidewire.

- 5 8. An embolic protection system as claimed in claim 7 wherein the guidewire abutment is located at the distal end of the guidewire.

- 10 ~~Sub B2~~ 9. An embolic protection system as claimed in claim 7 or 8 wherein the guidewire abutment is located proximal of the distal end of the guidewire.

- 15 10. An embolic protection system as claimed in any of claims 6 to 9 wherein the engagement element of the filter comprises a filter abutment on the filter.

- 20 11. An embolic protection system as claimed in claim 10 wherein the filter abutment is a distal abutment on the filter.

- 25 12. An embolic protection system as claimed in claim 10 wherein the filter abutment is a proximal abutment on the filter.

- ~~Sub B4~~ 13. An embolic protection system as claimed in any of claims 10 to 12 wherein the tubular guidewire path is defined by a sleeve and the filter abutment is provided by the sleeve.

14. An embolic protection system as claimed in any preceding claim wherein the engagement elements comprise releasable locking elements.

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15. An embolic protection system as claimed in claim 14 wherein the releasable locking elements comprise a taper lock.
- 5 16. An embolic protection system as claimed in claim 15 wherein the guidewire engagement element comprises a locking ring on the guidewire and the filter engagement element comprises a tapered surface of the filter, the locking ring having a tapered surface which is engagable with the tapered surface of the filter to lock the filter to the
- 10 guidewire.
17. An embolic protection system as claimed in claim 16 wherein the locking ring is a split ring.
- 15 *Sub B5* 18. An embolic protection system as claimed in claims 16 or 17 including a tube advancable over the guidewire, the locking ring being located between a distal end of the tube and the filter for retrieval of the filter.
- 20 19. An embolic protection system as claimed in any of claims 15 to 18 wherein the releasable locking means includes a tether engagable with the filter for retrieving the filter into the retrieval catheter.
- 25 20. An embolic protection system as claimed in any preceding claim comprising deployment means for moving the collapsed filter relative to the distal end of the delivery catheter.
21. An embolic protection system as claimed in claim 21 wherein the deployment means comprises a tube which is advancable over the

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guidewire for engagement with the proximal end of the filter, the tube being movable longitudinally relative to the delivery catheter for deployment of the filter from the distal end of the delivery catheter.

5      22. An embolic protection system as claimed in any preceding claim including loading means for loading the filter into the delivery catheter.

10      23. An embolic protection system as claimed in claim 22 wherein the loading means comprises a funnel having a narrowed portion disposed at the distal end of the delivery catheter and an enlarged portion for receiving a proximal portion of the filter in the expanded configuration, the filter being progressively collapsed as it is moved through the funnel for loading into the delivery catheter.

15      24. An embolic protection system as claimed in any preceding claim including engagement means for engaging the filter within the retrieval catheter.

20      25. An embolic protection system as claimed in claim 24 wherein the engagement means comprises a frictional engagement between the filter body and an internal surface of the distal end of the retrieval catheter.

25      26. An embolic protection system as claimed in claim 24 or 25 wherein the engagement means comprises projections on the inner surface of the retrieval catheter adjacent the distal end thereof.

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27. An embolic protection system as claimed in any preceding claim wherein the delivery catheter includes an elongate slot disposed in a first sidewall thereof at a first distal location which is spaced a relatively longer distance from the proximal end of the delivery catheter than from the distal end of the delivery catheter, and wherein the inner deployment catheter includes an aperture disposed in a second sidewall thereof at a second distal location which substantially corresponds with said first distal location for said elongate slot, thereby permitting co-operative movement of said filter with respect to said guidewire and associated delivery and deployment catheters for selective deployment of the filter while facilitating the rapid exchange of said catheter and filter assembly over a guidewire without the utilisation of exchange wires or extension wires.
28. An embolic protection system as claimed in any preceding claim wherein the embolic protection filter comprises a collapsible filter body, the proximal inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body, the distal outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body.
29. An embolic protection system as claimed in claim 28 where the filter comprises a collapsible filter support frame having a proximal end and a distal end, the filter support frame being movable between a collapsed position for movement during delivery through the vascular system and an extended outwardly projecting position to support the

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filter body in an expanded position thereby urging the filter body into apposition with the vasculature upon deployment.

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An embolic protection system as claimed in claim 28 or 29 comprising a guide olive provided at the distal end of the filter body.

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31. An embolic protection system as claimed in claim 30 comprising an inner elongate sleeve to which the filter body and the filter support frame are mounted, the sleeve having a proximal end and a distal end, the guide olive extending distally of the sleeve distal end.

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32. A system as claimed in claim 31 wherein the proximal end of the filter support frame and the inlet end of the filter body are attached to the proximal end of the sleeve.

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A system as claimed in any of claims 30 to 32 wherein the guide olive is integral with the filter body.

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34. A system as claimed in any of claims 30 to 33 wherein the guide olive tapers distally inwardly.

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35. An embolic protection system substantially as hereinbefore described with reference to the accompanying drawings.

36. A method for the capture and removal of embolic material from a blood vessel during an interventional procedure comprising the steps of:-

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advancing a guidewire through a vasculature;

crossing a desired treatment location with the guidewire;

5 introducing over the guidewire a collapsible embolic protection filter having a collapsed configuration, the collapsed configuration permitting delivery and withdrawal of the filter;

deploying the filter distal to the treatment location;

10 carrying out the interventional procedure, embolic material generated during the treatment procedure being captured by the deployed filter;

15 advancing a retrieval catheter over the guidewire;

collapsing the filter into the retrieval catheter and with it the captured embolic material;

20 withdrawing the retrieval catheter and the collapsed filter from the vasculature leaving the guidewire in the vasculature.

37. A method as claimed in claim 36 comprising the step of providing a catheter over the guidewire after withdrawal of the retrieval catheter.

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~~A method as claimed in claim 36 or 37 including the step of moving the guidewire after withdrawal of the retrieval catheter and the~~



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collapsed filter from the vasculature to re-position the guidewire in the vasculature.

39. A method as claimed in claim 37 or 38 wherein the catheter is a catheter for delivery of a diagnostic medium.

40. A method as claimed in claim 37 or 38 wherein the catheter is a catheter for delivery of a lytic agent.

41. A method as claimed in any of claims 36 to 40 wherein the filter is slidably disposed on the guidewire when the filter is in the expanded deployed configuration.

42. A method as claimed in any of claims 36 to 41 wherein the filter is rotatably disposed on the guidewire when the filter is in the expanded deployed configuration.

43. A method as claimed in any of claims 36 to 42 including the steps of:-

loading the filter in a collapsed configuration within a delivery catheter;

advancing the delivery catheter and filter over the guidewire to deliver the filter to a desired location; and

deploying the filter from the delivery catheter at the desired location.

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44. A method as claimed in claim 43 including the steps of:-

collapsing the filter from an expanded configuration for loading the filter into the delivery catheter;

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the filter being expanded to a deployment configuration on release from the delivery catheter.

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45. A method as claimed in any of claims 36 to 44 wherein the treatment location is a region of stenosis.

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46. A method as claimed in claim 45 wherein the interventional procedure includes a balloon dilation of the stenosis while the filter is deployed.

47. A method as claimed in claim 45 wherein the interventional procedure includes a stenting of the treatment location while the filter is deployed.

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48. A method for the capture and removal of embolic material from a blood vessel substantially as hereinbefore described with reference to the accompanying drawings.

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49. A medical catheter for transvascular delivery and deployment of an embolic protection filter, the catheter comprising:-

an outer catheter tube defining a distal end; and

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an inner catheter tube defining a distal end;

the outer tube being at least partially movable relative to the inner tube between a delivery configuration in which the distal end of the outer tube extends distally of the distal end of the inner tube to define a reception space for an embolic protection filter within the outer tube, and a deployment configuration in which the distal end of the inner tube extends distally of the distal end of the outer tube for deployment of the embolic protection filter ;

the inner catheter tube providing compressive resistance and the outer catheter tube providing stretch resistance.

15      50.    A catheter as claimed in claim 49 wherein the inner catheter tube at least partially comprises a relatively stiff core encased in a more pliable body.

20      51.    A catheter as claimed in claim 49 or 50 wherein the outer catheter tube at least partially comprises a relatively stiff core encased in a more pliable body.

25      52.    A catheter as claimed in claim 50 or 51 wherein the core is oriented to prevent elongation of the outer catheter tube and/or compression of the inner catheter tube.

53.    A catheter as claimed in any of claims 49 to 52 wherein the core comprises a mesh.

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57. A catheter as claimed in claim 56 wherein the metal is stainless steel.

58. A catheter as claimed in any of claims 50 to 57 wherein the pliable body is of a plastics material.

59. A catheter as claimed in claim 58 wherein the plastic is polyamide.

60. A medical catheter for transvascular delivery and deployment of an embolic protection filter substantially as hereinbefore described with reference to the accompanying drawings.

61. An embolic protection device comprising:

a collapsible filter element for delivery through a vascular system of a patient;

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the filter element comprising a collapsible filter body and a collapsible filter support frame contacting the filter body;

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the filter body having an inlet end and an outlet end, the inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body, the outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body;

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the filter support frame being movable between a collapsed position for movement through the vascular system and an extended outwardly projecting position to support the filter body in an expanded position;

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the frame having an intermediate section to urge the filter body in the expanded position into apposition with a vessel wall, and a proximal section extending radially inwardly of the intermediate section;

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at least part of the proximal section of the frame being spaced distally to accommodate inflow of embolic material through the inlet openings in the expanded position.

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62. A device claimed in claim 61 wherein the filter body comprises one or more linking webs between adjacent inlet openings, and a part of the proximal section of the frame extends radially inwardly in alignment with the webs.

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63. A device as claimed in claims 61 or 62 wherein the frame proximal section comprises one or more frame elements, at least one frame element providing the part of the proximal section spaced distally.

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64. A device as claimed in claim 62 or 63 wherein at least one frame element provides the part of the proximal section extending radially inwardly in alignment with a linking web between adjacent inlet openings.

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65. A device as claimed in claim 64 wherein the number of frame elements is four, two frame elements extending radially inwardly in alignment with two webs between two inlet openings, and two frame elements spaced distally of the inlet openings.

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66. A device as claimed in any of claims 61 to 65 wherein the support frame is gold-plated and electropolished.

67. An embolic protection device substantially as hereinbefore described with reference to the accompanying drawings.

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